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No. 96-1340

IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

IRENE M. GREEN, *et al.*,
Petitioners,

v.

RICHARD L. DOLSKY and COLLAGEN CORPORATION,
Respondents.

On Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

BRIEF OF COLLAGEN CORPORATION IN RESPONSE TO PETITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts common law claims challenging the safety or effectiveness of a medical device that the Food and Drug Administration has found to be safe and effective and has approved for marketing pursuant to the premarket approval process under 21 U.S.C. § 360e(c).*

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* Respondent Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

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BRIEF OF COLLAGEN CORPORATION IN RESPONSE TO PETITION

STATEMENT

1. *Company history and regulatory background.* In the early 1970s, a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized respondent Collagen Corporation ("Collagen") to manufacture and distribute collagen products to be used in various medical treatments. The product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct

or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to regulation under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360*l*. As this Court has noted,

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," which is known as the "premarket approval," or "PMA" process, is a rigorous one.

Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2246-47 (1996).

The PMA process entails an exhaustive investigation into safety and effectiveness with respect to (1) the persons for whose use the device is intended and (2) the conditions of use prescribed, recommended, or suggested in the labeling of the device. 21 U.S.C. § 360c(a)(2). An applicant who seeks the FDA's approval to market a Class III device must provide:

> (A) full reports of all information, published or known to . . . the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
>
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation of, such device;
>
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture [and] processing . . . of such device;
>
> (D) . . . adequate information to show that . . . such device fully meets [pertinent] performance standard[s];

> (E) . . . samples of such device . . .;
>
> (F) specimens of the labelling proposed to be used for such device; and
>
> (G) such other information . . . as the [FDA] . . . may require.

21 U.S.C. § 360e(c)(1).

The application for premarket approval also must include, *inter alia,* a "general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended," an "explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device," and a "description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended." 21 C.F.R. § 814.20(b)(3). The application must be periodically updated "with new safety and effectiveness information learned about the device from ongoing or completed studies." 21 C.F.R. § 814.20(e).

A completed application is reviewed by a panel of experts. 21 U.S.C. § 360e(c)(2). After considering the panel's report and recommendation, the FDA will grant the application only if it finds reasonable assurance (1) that the device is safe and effective with respect to both the persons for whose use the device is intended and the conditions of use prescribd, recommended, or suggested in its labeling, (2) that the manufacturing and processing methods and facilities are satisfactory, and (3) that the proposed labeling is not false or misleading in any manner. 21 U.S.C. §§ 360c(a)(2) and 360e(d)(2); *see also* 21 C.F.R. § 814.44.

Collagen filed an application with the FDA for premarket approval of Zyderm on April 30, 1980. Its application included, *inter alia,* the results of clinical testing

in over five thousand human subjects. R. 48b, 67b-91b ("R." refers to the record in the court below). Following more than one year of detailed investigation, the FDA found Zyderm to be safe and effective and approved it for marketing. 46 Fed. Reg. 46394 (1981). The FDA's approval order for Zyderm set forth numerous "conditions of approval," including the following:

> *Before making any change that may affect the safety or effectiveness* of the device, [Collagen must] submit a supplemental PMA for review and approval by FDA. Such changes include, but are not limited to:
>
> (1) new indications for use;
>
> (2) labeling changes;
>
> (3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;
>
> (4) changes in sterilization procedures;
>
> (5) changes in packaging;
>
> (6) changes in the performance or design specifications, circuits, parts, components, accessories, ingredients, or physical layout of the device.

R. 452b-456b. Since 1981, Collagen has marketed Zyderm as a prescription-only medical device pursuant to the authority granted by the FDA in this approval order. In 1991, the FDA reviewed Zyderm's record and reconfirmed its initial finding of safety and effectiveness. R. 42b-43b.

2. *Proceedings in this case.* In March 1989, petitioner Irene Green was treated with Zyderm by her physician, respondent Richard Dolsky. Pet. App. 33. In May 1992, she and her husband brought suit against Dolsky and Collagen in the Court of Common Pleas of Montgomery County, Pennsylvania, claiming that the treatment had caused an autoimmune disorder. *Id.* Relief was sought

under state tort law theories of negligence, strict liability, breach of warranty, and fraud. *Id.* at 19.

Collagen moved for summary judgment on the ground that petitioners' tort claims were barred by the MDA pre-emption statute, 21 U.S.C. § 360k(a). That statute bars states from imposing, with respect to a medical device, "any requirement—(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." The trial court granted Collagen's motion, holding that petitioners' claims were barred for the reasons stated in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied,* 114 S. Ct. 86 (1993), and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied,* 114 S. Ct. 84 (1993). Pet. App. 33-34.

The Superior Court of Pennsylvania affirmed. Pet. App. 32. The court explained:

> a finding in favor of the Greens on any of their alleged state tort law claims would impose additional or different requirements on Collagen, whose product, Zyderm, has already received FDA approval. Such requirements are in conflict with the MDA and thus, the Greens' state law claims are therefore preempted.

Id. at 29. In reaching this conclusion, the Court considered and rejected petitioners' "six disparate arguments seeking to overcome federal preemption." *Id.*

Following this Court's decision in *Lohr,* the Supreme Court of Pennsylvania reversed and remanded for further proceedings. Pet. App. 15. The court noted that *Lohr* "has resolved at least some of the questions involved in this case." *Id.* at 7. But the court also noted that *Lohr* "is not wholly applicable" because it involved a medical device that had been approved for marketing under 21 U.S.C. § 360e(b)(1)(B) (the "§ 510(k) notification

process") as substantially equivalent to a device already on the market and thus, unlike Zyderm, had not been subject to an investigation into safety and effectiveness. *Id.* at 10.

The court concluded that petitioners' claims of negligent development, failure to warn, and mislabeling were "impermissible because they attempt to substitute a reasonableness analysis characteristic of negligence claims for the judgment of the FDA in approving the development and distribution of this particular product in the course of its premarket approval process." *Id.* at 12. Similarly, the court determined that petitioners' claims of strict liability and breach of warranty also were contrary to the FDA's findings of safety and effectiveness and sought the imposition of state requirements different from or in addition to those imposed by the FDA. *Id.* at 14. On the other hand, the court held that petitioners' various claims to the effect that Collagen had "fraudulently completed the premarket approval process," *id.* at 13 n.7, or had failed to monitor patients treated with Zyderm, were not preempted because such claims "in essence, mirror FDA requirements." *Id.* at 12; *see also id.* at 14 n.8. The court further concluded that petitioners' claims against Dr. Dolsky "are permissible medical malpractice claims." *Id.* at 15.

DISCUSSION

A careful inquiry into safety and effectiveness is the hallmark of the FDA's "rigorous PMA process." *Lohr*, 116 S. Ct. at 2247. The Pennsylvania Supreme Court held that once the FDA has approved a medical device pursuant to the PMA process, 21 U.S.C. § 360k(a) bars common law causes of action that, in effect, ask a jury to second-guess the FDA's own determination of safety and effectiveness. That holding is both correct and fully consistent with *Lohr*.

This Court nonetheless may wish to grant plenary review. The case affords the Court an opportunity to decide,

once and for all, the proper scope of the MDA preemption statute as applied to medical devices that the FDA has found to be safe and effective and has approved for marketing pursuant to the PMA process. The question is one of substantial importance, and it arises with great frequency. Moreover, as petitioners note, the decision below directly conflicts with at least one post-*Lohr* decision by a state court of last resort, *Fiore v. Collagen Corp.*, 1996 WL 343648 (Ariz. App. 1996), *appeal denied* (Ariz. Jan. 14, 1997). *See* Pet. 13. Collagen therefore acquiesces in petitioners' request that their petition be granted.

If the petition is granted, the Court also should grant Collagen's conditional cross-petition. The petition and cross-petition, taken together, will enable the Court to consider MDA preemption in the context of the full range of claims commonly asserted in cases of this sort.

I. THE MDA PREEMPTS COMMON LAW CLAIMS CHALLENGING THE SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES THAT THE FDA HAS APPROVED FOR MARKETING PURSUANT TO THE PMA PROCESS

The medical device at issue in *Lohr* had not been scrutinized for safety and effectiveness pursuant to the PMA process. Instead, the device had been cleared for marketing pursuant to the § 510(k) notification process upon a determination that it was substantially equivalent to a device already on the market. The case presented two broad questions: first, whether state law tort claims impose "requirements," within the meaning of 21 U.S.C. § 360k(a), that are potentially subject to preemption; and second, if so, whether the § 510(k) notification process imposes federal "requirements," also within the meaning of the statute, sufficient to preempt such claims. *See Lohr*, 116 S. Ct. at 2259 (Breyer, J., concurring).

A majority of the Court in *Lohr* determined that common law causes of action do impose "requirements"

within the meaning of 21 U.S.C. § 360k(a) and thus may be subject to preemption. *Lohr*, 116 S. Ct. 2262-63 (O'Connor, J., concurring and dissenting) ("the term 'requirement' encompasses state common-law causes of action"); *id.* at 2259-60 (Breyer, J., concurring) ("the MDA will sometimes pre-empt a state-law tort suit"). The court below correctly adopted this construction of the MDA preemption statute. See Pet. App. 9-11.

This Court laid the foundation for its consideration of the second general question in *Lohr*, concerning the nature of the particular federal requirements there at issue, by contrasting the truncated § 510(k) notification process with the far more elaborate PMA process involved in this case:

> [Under the PMA process, m]anufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. . . .
>
> . . . The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. As one commentator noted, '[t]he attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.'

Lohr, 116 S. Ct. (citations omitted). Consequently, the court reasoned, the manufacturer's claim of preemption in *Lohr* "exaggerates the importance of the § 510(k) process." *Id.* at 2254.

The § 510(k) notification process " 'is focused on *equivalence*, not safety.' " *Lohr*, 116 S. Ct. at 2254 (emphasis in original). A device approved for marketing

pursuant to that process "has never been formally reviewed under the MDA for safety or efficacy." *Id.* The Court therefore determined that requiring "the manufacturer of the device . . . to defend itself against state-law claims of negligent design" would not interfere with the federal regulatory scheme. *Id.* at 2255; *see also id.* at 2263-64 (O'Connor, J., concurring and dissenting) ("Because the § 510(k) process seeks merely to establish whether a pre-1976 device and a post-1976 device are equivalent, and places no 'requirements' on a device, the Lohrs' defective design claim is not preempted"). The Court further determined that, as applied to a device approved for marketing pursuant to the § 510(k) notification process, "general federal regulations governing the labeling and manufacture of all medical devices," *id.* at 2256, are insufficiently specific to have preemptive effect standing on their own:

> [T]he[se] federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 2258.

The decision below is consistent with this analysis. In *Lohr,* this Court drew support from the FDA's determination that state and local regulations are preempted when the agency "has established specific counterpart regulations or there are other specific requirements applicable to a particular device." 21 C.F.R. § 808.1(d). *See Lohr,* 116 S. Ct. at 2257. The FDA itself has explained that for Class III medical devices like Zyderm, "the counterpart FDA requirement [is] that the product have premarket approval." 43 Fed. Reg. 18661, 18664 (1978). In addition, as the facts of this case demonstrate, the marketing approval order generated by the PMA process imposes numerous specific requirements applicable to the particular device.

A PMA approval order represents a license to market the approved medical device strictly in accordance with the conditions specified by the FDA to ensure safety and effectiveness. By regulation, "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. In other words, the specifications in a PMA application become, upon approval, binding federal requirements. This means, as the court below recognized, that Collagen, in producing and selling Zyderm, must adhere to all the specifications in its PMA application relating to indications for use, proposed labeling, manufacturing methods and facilities, sterilization procedures, packaging, ingredients, and performance and design. Pet. App. 11. *See also, e.g., King*, 984 F.2d at 1134 ("it is clear that the FDA has imposed requirements on Zyderm relating to labeling, design, manufacturing and other aspects of the device"). Under 21 U.S.C. § 360k (a), these detailed and device-specific requirements have preemptive effect.

In concluding that such federal requirements give rise to preemption, the court below was in good company. Virtually every federal court of appeals that has considered the issue has held that the comprehensive PMA process, together with the detailed conditions imposed on a manufacturer as a result of that process, constitute specific requirements that have preemptive effect under 21 U.S.C. § 360k(a). *See, e.g., Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995) (PMA procedures impose "specific requirements applicable to a particular device under the act"); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995) ("The premarket approval process is a specific requirement for a device within the meaning of 21 U.S.C. § 360k(a)"); *Stamps*, 984 F.2d at 1421-22 & n.3, 1424 & n.8; *Mitchell*

v. Collagen Corp., 67 F.3d 1268, 1279 (7th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1966); *contra, Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996).

Claims based upon theories of strict liability, negligence, mislabeling, failure to warn, express and implied warranty, and so forth, are all, at bottom, claims that the medical device was not safe and effective and should have been designed, manufactured, packaged, labeled, or sold in a manner different from that both explicitly approved by the FDA upon finding the device safe and effective and explicitly required by the FDA as a condition of continued marketing. The central purpose of the MDA preemption statute is to protect manufacturers like Collagen from conflicting demands of this sort. That statute does not permit the FDA's painstakingly meticulous PMA process, and the detailed and comprehensive requirements that the FDA imposes as a result of that process, to be supplanted by the notoriously unscientific process of trial by jury. *See* Pet. App. 12.

II. THE QUESTION PRESENTED IS RECURRENT AND IMPORTANT

This Court granted certiorari in *Lohr* because the federal courts of appeals were in conflict concerning whether the § 510(k) notification process creates preemptive "requirements" within the meaning of 21 U.S.C. § 360k(a). *Lohr*, 116 S. Ct. at 2250 n.6. That conflict was resolved by *Lohr*. But as the decision below and the ruling of the Arizona Supreme Court in *Fiore* demonstrate, the lower courts are unlikely to achieve unanimity in applying the precepts of *Lohr* to cases involving the very different PMA process.

Before the decision in *Lohr*, the First, Third, Fifth, Seventh, and Eighth Circuits all had held that the requirements imposed by the FDA pursuant to the PMA process

are preemptive. *See* pages 10-11, *supra*. Only the Ninth Circuit in *Kennedy* had reached the contrary result. Although the issue currently is pending before the Seventh Circuit on remand in *Mitchell*, no federal court of appeals has yet decided this issue in light of *Lohr*. However, in the closely related context of the investigational device exemption ("IDE") under 21 U.S.C. § 360j(g), the Sixth Circuit recently held that the MDA preemption statute bars common law claims of the kind asserted by petitioners here. *Martin v. Telectronics Pacing Systems, Inc.*, 1997 WL 35041 (6th Cir. Jan. 31, 1997). This indicates that the existing circuit conflict with respect to the PMA process will not simply fade away.

To say that the issue is recurrent, moreover, would be a considerable understatement. The issue arises whenever a tort claim is filed against the manufacturer of a medical device that the FDA has found to be safe and effective. Collagen alone has been forced to litigate the scope of MDA preemption in no less than four federal courts of appeals (*King* (1st Cir.); *Stamps* (5th Cir.); *Mitchell* (7th Cir.); and *Kennedy* (9th Cir.)) and additionally in four state courts of last resort (this case (Penn.); *Fiore* (Ariz.); *Mears v. Marshall*, 324 Or. 130, 921 P.2d 966 (1996); and *Worthy v. Collagen Corp.*, 921 S.W.2d 711 (Tex. App.-Dallas 1995), *writ granted*, 40 Tex. Sup. Ct. J. 94 (Nov. 15, 1996)). This repetitive litigation has been burdensome for Collagen and for the courts as well. Other manufacturers of medical devices, and other federal and state courts, face the same problem.

Petitioners' suggestion that there should be a summary disposition of this case, Pet. 14-15, is not responsible. Because of the wide differences between the PMA process and the § 510(k) notification process, this case cannot be decided solely on the basis of a rote application of *Lohr*. This case nonetheless is a suitable vehicle for the resolution of the scope of MDA preemption in cases involving medical devices found to be safe and effective

and approved for marketing pursuant to the PMA process. In view of the unquestioned importance and recurrent nature of the question presented, it would be appropriate for the Court to grant plenary review in order to decide that question in this case.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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